

Exercise for Fall Risk Reduction in Community-Dwelling Older Adults: A Systematic Review

Catherine M. Arnold, Meena M. Sran, Elizabeth L. Harrison

ABSTRACT

Purpose: To evaluate the influence of exercise on falls and fall risk reduction in community-dwelling older adults and to present an updated synthesis of outcome measures for the assessment of fall risk in community-dwelling older adults.

Method: A systematic review was performed, considering English-language articles published from 2000 to 2006 and accessible through MEDLINE, CINAHL, PEDro, EMBASE, and/or AMED. Included were randomized controlled clinical trials (RCTs) that used an exercise or physical activity intervention and involved participants over age 50. Screening and methodological quality for internal validity were conducted by two independent reviewers.

Results: The search retrieved 156 abstracts; 22 articles met the internal validity criteria. Both individualized and group exercise programmes were found to be effective in reducing falls and fall risk. The optimal type, frequency, and dose of exercise to achieve a positive effect have not been determined. A variety of outcome measures have been used to measure fall risk, especially for balance.

Conclusions: Falls and fall risk can be reduced with exercise interventions in the community-dwelling elderly, although the most effective exercise variables are unknown. Future studies in populations with comorbidities known to increase fall risk will help determine optimal, condition-specific fall-prevention programmes. Poor balance is a key risk factor for falls; therefore, the best measure of this variable should be selected when evaluating patients at risk of falling.

Key Words: accidental falls, exercise, fall risk, systematic review

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RÉSUMÉ

Objet : Évaluer l'influence de l'exercice sur les chutes et sur la réduction du risque de chute chez les aînés qui vivent dans la communauté et présenter une synthèse à jour des mesures d'impactes pour l'évaluation du risque de chute chez les aînés qui vivent dans la communauté.

Méthodologie : Une étude méthodique a été effectuée d'après des articles en anglais qui ont été publiés de 2000 à 2006 et accessibles par le truchement de MEDLINE, CINAHL, PEDro, EMBASE et/ou AMED. On a inclut des essais cliniques aléatoires (EAC) contrôlés qui utilisaient intervention par exercice ou par activité physique et comprenaient des participants âgés de plus de 50 ans. La sélection et la qualité méthodologique pour la validité interne étaient conduites par deux évaluateurs indépendants.

Résultats : La recherche a repéré 156 résumés ; 22 articles satisfaisaient au critère de validité interne. Les programmes d'exercice individualisés et en groupe se sont avérés efficaces dans la réduction des chutes et du risque de chute. Le type, la fréquence et la dose optimal d'exercices requis pour obtenir un effet positif n'ont pas été déterminés. Diverses mesures d'impactes ont été utilisées pour mesurer le risque de chute, surtout pour l'équilibre.

Conclusion : Les chutes et le risque de chute peuvent être réduits par des interventions d'exercices chez les aînés qui vivent dans la communauté bien que les variables des exercices les plus efficaces soient encore inconnues. Des études futures au sein des populations ayant des comorbidités reconnues comme élevant le risque de chute aideront à déterminer les programmes optimaux de prévention de chute axés sur des conditions spécifiques. Un mauvais équilibre est un facteur de risque clé pour les chutes ; donc, la meilleure mesure de cette variable devrait être choisie lorsque les patients à risque de chute sont évalués.

Mots clés : chutes accidentelles, étude méthodique, exercice, risque de chute

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INTRODUCTION

Thirty percent of adults over the age of 65 and 50% of adults over the age of 80 fall annually.¹ Not only the high incidence of falling in older adults but also the combination of that high incidence with higher susceptibility to injury from a fall are of concern. Despite representing only 12% of the trauma population, the elderly sustain a disproportionate percentage of serious injury from trauma, accounting for nearly 30% of all deaths.² Falls result in substantial costs to the individual, his or her family, and the health care system, accounting for 77% of all elderly injury-related hospital admissions (and 57% of injury-related deaths in women and 36% in men in Canada).^{3,4}

The effects of fall intervention programmes, including exercising independently or as part of a multi-factorial programme, have been assessed in several high-quality trials and synthesized in previous systematic reviews and meta-analyses.^{5–8} These reviews included only those studies that measured fall numbers or fall rates as outcomes, thereby excluding studies that measured fall risk using tools designed to quantify factors such as balance or muscle strength as a surrogate measure of fall reduction.^{5,9} Because clinical practice guidelines support measurement of fall risk, it is important that more attention be given to these outcomes.¹ Since 2000, there has been a surge of randomized controlled trials (RCTs) evaluating the effect of both group and individualized exercise on fall rates and fall risk factors. These studies have expanded their inclusion criteria to consider community-dwelling elderly subjects with and without impairments that could increase their risk of falling. No previous review has included these recent studies with the aim of critically appraising the new evidence in this field.

Building on a previous Cochrane systematic review on the prevention of falls,⁵ the present review was designed to (1) evaluate the influence of exercise on falls and fall risk reduction in community-dwelling older adults and (2) present a synthesis of outcome measures for the assessment of fall risk in community-dwelling older adults.

METHODS

The primary search strategy considered (1) MEDLINE, CINAHL, PEDro (EMBASE), and AMED databases; (2) articles published from January 2000 to July 2006; (3) articles published in English; and (4) keywords including “accidental falls,” “risk factors,” “exercise,” “rehabilitation,” “physical activity,” “physical fitness,” “physical performance,” “sports,” “motor activity,” “exercise techniques,” and “physical therapy techniques.” The initial search retrieved 156 abstracts.

Figure 1 documents the steps used in the search strategy. Two authors (MS and EH) independently

reviewed the 156 abstracts to determine whether each study met the following criteria:

1. Study was an RCT, including studies that used either a control group (activity or treatment as usual), a sham control group, or another intervention that did not include exercise (e.g., education).
2. Study included exercise or physical activity intervention.
3. Study included community-dwelling older adults.
4. Study participants were over age 50.

For the purposes of this review, “community-dwelling” was defined as ambulatory and not relying on someone else for basic activities of daily living or walking. If there was a discrepancy in the rating of the abstract ($n=16$), the third author (CA) arbitrated. Of the 156 abstracts reviewed, 39 met all four criteria. These 39 articles were reviewed for quality, by two independent reviewers, based on criteria set out by van Tulder et al.¹⁰ (refer to Appendix A for a list of these criteria). The methodological quality cutoff score for inclusion in the review was set at 50% of the internal validity criteria.¹⁰ There are no clear guidelines for an ideal cutoff score, but, after consideration of the criteria, the authors selected 50% as a cutoff in order to include studies that might have lower internal validity scores. The reason for accommodating to a lower internal validity score was that some of the criteria, such as blinding of subjects to exercise intervention, are not practical for this type of study. A final quality score out of 17 was determined for each study (see Appendix A). Any discrepancies in quality ratings were resolved independently by a third reviewer. A process for adjudicating rater differences regarding study acceptability was predetermined, but it was not required. Although 39 studies were reviewed for quality, four were based on the same study sample and intervention; therefore, only the most recent of these publications was included. Of the 35 studies included in the quality review, 13 were excluded because they did not meet 50% of the internal validity criteria. Table 1 summarizes the populations, methodologies, and findings of the 22 studies included in the review. Table 2 summarizes specific aspects of the population and intervention, including age, health status, group or individual intervention, and length of intervention.

RESULTS

Quality of Studies

The range of quality ratings was 9–15 out of a possible 17 points. The median quality score for the 22 studies reviewed was 13. Internal validity scores ranged from 5 to 8 out of a possible 10 points, with a median score of 6. For exercise intervention studies, it is very difficult to achieve an internal validity score higher than 8 or a

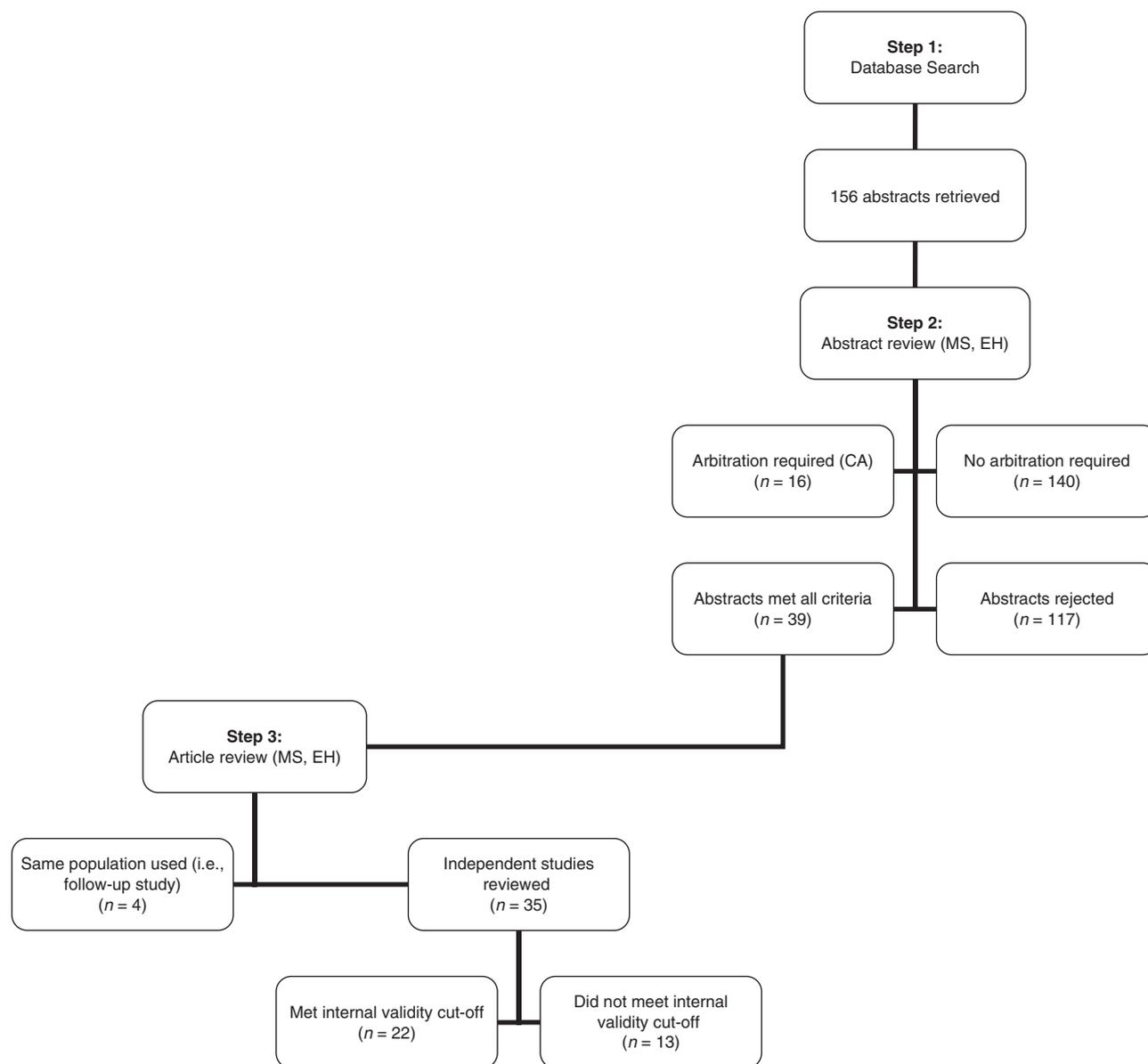


Figure 1 Steps used in the search strategy

total score higher than 15, since blinding the caregiver and the patient to the intervention is not possible.

Population

Of the 35 studies, four included adults aged 50 years or older, 11 included adults aged 65 or older, and seven included adults over the age of 75. In 11 of the studies, a standard method of screening for fall risk was used and at least one fall risk factor was part of the inclusion criteria (i.e., inclusion criteria included a history of a fall in the past year or lower performance on a functional test such as walking or balance). In addition, six studies included populations with a secondary condition (one with visual impairment, two with stroke, two with osteoporosis, and one with a recent history of bed

rest or hospitalization). The remaining 16 studies included a healthy older adult population; however, it is not known whether these samples may have included individuals with fall risk factors such as osteoporosis, arthritis, more subtle degrees of neurological impairment, or visual impairment. The study samples included in this review represent the diversity of community-dwelling older adults seen by physical therapists. Although most studies included both male and female participants, the ratio of women to men was 3:1 or 4:1.

Outcomes Used

Six categories were used to describe fall risk: (1) muscle strength (isolated strength measurement, typically lower body strength); (2) functional tasks, including

Table 1 Summary of 22 Studies Included in the Final Review

First Author/Year	Participants	Intervention	Falls Outcomes	Fall Risk Outcomes	Results	Quality Rating
Barnett 2003 ¹²	N= 163 F:M 3:1 (2:1 control) Mean age: 74.4 yrs Inclusion: ≥ 1 physical impairment, age ≥ 65 yrs	1 yr <i>Experimental:</i> 1 \times /wk, 60 min, total of 37 classes; included balance, coordination, aerobic capacity, muscle strength, warm-up, stretch, home programme, and education on fall risk. <i>Control:</i> written information on fall prevention.	Fall rate and number of falls, multiple fallers, and injurious falls in 12 mos Monthly postal survey	<i>Muscle strength:</i> knee extension, ankle dorsiflexion (spring gauge isometric) <i>Functional task:</i> chair stands <i>Static balance:</i> sway at waist level (posturography) <i>Dynamic balance:</i> reaction time, step-up ability (BBS), coordinated stability test <i>Gait:</i> 6 m walk <i>Self-report function:</i> SF-36, PASE	<i>Falls:</i> Improved for fall rate and number of multiple fallers; no change for number of injurious falls <i>Fall risk:</i> Inconsistent—3/6 balance tests improved: static sway (2 conditions) and coordinated stability test <i>Conclusion:</i> Participants in weekly exercise can improve balance and decrease fall rate after 6 months.	Total: 13/17 Internal validity: 6/10
Brouwer 2003 ¹³	N= 38 F:M 3:1 Age range: 67–87 yrs Inclusion: Reported fear of falls and activity curtailment (ABC and Human Activity Profile)	8 wks <i>Experimental:</i> (1) education 1 \times /week for 1 hour; (2) exercise 1 \times /week for 1 hr: low resistance strengthening/balance <i>Control:</i> (1) education 1 \times /week for 1 hour	No	<i>Muscle strength:</i> Isokinetic (Biodex) hip, knee, ankle <i>Static balance:</i> displacement of COP eyes open and closed (force platform) <i>Dynamic balance:</i> COP displacement forward, back, side lean <i>Gait:</i> walking speed 20 m. <i>Self-report function:</i> SF-36, HAP <i>Falls efficacy:</i> ABC	<i>Fall risk:</i> Inconsistent—medial-lateral and anterior-posterior sway improved for activity group > education; both groups improved in ABC <i>Conclusion:</i> Both activity and education improve balance confidence; only activity resulted in any physical gain in balance after 6 weeks.	Total: 14/17 Internal validity: 8/10
Campbell 2005 ²⁹	N= 391 F:M 3:1 Age range: 75–96 yrs Mean 83.6 yrs Inclusion: ≥ 75 , visual acuity 6/24 (Snellen eye chart)	1 yr <i>Experimental:</i> (1) home safety, OT visits in home; (2) exercise prescribed at home, individualized muscle strengthening and balance + vitamin D supplement; (3) both 1 and 2 <i>Control:</i> attention only (social visit twice)	Number of falls, injurious falls, monthly postcard calendars, economic evaluation		<i>Falls:</i> Improved for home safety, not for exercise only; combined programme resulted in home safety's being less effective if exercise added <i>Conclusion:</i> For the visually impaired older adult, home safety has benefit in reducing fall rates; home exercise does not.	Total: 12/17 Internal validity: 6/10
Carter 2002 ¹⁴	N= 93 100% F Inclusion: Age 65–75 yrs, female, not engaged in weekly moderate exercise, OP (bone density >2.5 SD hip or spine)	20 wks <i>Experimental:</i> Osteofit 40 min, 2 \times /wk: posture, balance, gait coordination. <i>Control:</i> attention only (bimonthly social seminars)	Number of falls via calendars	<i>Muscle strength:</i> Knee extension (spring gauge) <i>Static balance:</i> sway (computerized posturography) <i>Dynamic balance:</i> timed 10 m figure-of-8 course <i>Self-report function:</i> physical activity 7-day recall, general health	<i>Falls:</i> No change, questionable power to detect change <i>Fall Risk:</i> Inconsistent <i>Improved:</i> Figure-8 run / knee extension strength <i>Conclusion:</i> Osteofit for 20 wks can improve balance and strength.	Total: 14/17 Internal validity: 7/10
Clemson 2004 ¹⁹	N= 310 F:M 4:1 Mean age: 78 yrs Inclusion: ≥ 70 yrs, fall in past year or reported concern about falls	14 mos <i>Experimental:</i> 7 2-hr programmes over 7 weeks; <i>Stepping On</i> = small group education, coping strategies, exercise (balance and strength) <i>Control:</i> attention only (2 social visits)	Number of falls Multiple falls (2 or more) Monthly calendar mailed	<i>Static balance:</i> Rhomberg test, eyes closed <i>Functional task:</i> TUG <i>Self-report function:</i> SF-36, PASE <i>Falls efficacy:</i> MFES, mobility efficacy, worry scale	<i>Falls:</i> Improved for fall rate <i>Fall risk:</i> Inconsistent—improved for more challenging falls efficacy tasks, but not for basic daily tasks; no effect on balance <i>Conclusion:</i> Community educational and exercise programme can reduce falls over 14 months.	Total: 14/17 Internal validity: 8/10

(Continued)

Table 1 Continued

First Author/Year	Participants	Intervention	Falls Outcomes	Fall Risk Outcomes	Results	Quality Rating
Davison 2005 ²⁵	N= 313 F:M 4:1 Mean age: 77 yrs Inclusion: 1 fall in past year, attended emergency department for fall-related event	? 1 yr <i>Experimental</i> : comprehensive assessment of fall risk followed by individualized OT home assessment and PT exercise prescription <i>Control</i> : treatment as usual	Number of falls Multiple falls Mortality Injury rates Fall-related hospital admissions	<i>Falls efficacy</i> : ABC	Falls: Improved for fall rate; no change in emergency or hospital admissions or number of recurrent falls Fall risk: Improved falls efficacy Conclusion: Multi-factorial intervention following a fall improves confidence and decreases fall rate but not proportion of recurrent falls.	Total: 13/17 Internal validity: 7/10
Day 2002 ³⁰	N= 1090 F:M not reported Inclusion: ≥ 70 yrs, living at home	15 wks <i>Experimental</i> : (1) 1 \times /wk for 1 hr group-based exercise, led by physical therapist—flexibility, leg strength and balance supplemented with home exercise; (2) home hazard management (home maintenance and staff visits); (3) vision improvement (referred for eye care as needed); (4) combinations of each of the above partnered and then all three combined (7 arms in total) <i>Control</i> : physical activity as usual	Time to first fall via monthly postcard diary	<i>Muscle strength</i> : knee extension (measure not defined)* <i>Dynamic balance</i> : coordinated stability test* <i>Falls efficacy</i> : MFES * Not measured for whole sample	Falls: Improved for exercise only and for any interventions combined with exercise Fall risk: Inconsistent—improvement in balance, strength after 15 wks for first 177 to complete. Not clear if significantly different than control groups at 15 wks or 18 mos. Falls efficacy not reported. Conclusion: 1 \times /wk, 15-wk group exercise with home exercise can decrease fall rate over 18 months; other interventions provide additive effect.	Total: 12/17 Internal validity: 6/10
Devereux 2005 ⁴¹	N= 50 100% F Age range: 65–82 yrs Mean age: 73 yrs Inclusion: ≥ 65 yrs, diagnosed with OP or osteopenia	10 wks <i>Experimental</i> : aquatic exercise 50 min, 2 \times /wk; included posture, gait, balance, tai chi in the water supplemented with 10 min of education on self-management <i>Control</i> : physical activity as usual		<i>Dynamic balance</i> : step test <i>Self-report function</i> : SF-36 <i>Falls efficacy</i> : MFES	Fall risk: Improved on positive step test, physical function, social function, mental health on SF-36; no change in MFES, pain, general health on SF-36 Conclusion: Aquatic exercise for 10 wks can improve dynamic balance.	Total: 12/17 Internal validity: 6/10
Gill 2002 ²⁶	N= 188 F:M 4:1 Mean age: 83 yrs Inclusion: ≥ 75 yrs; >10 -sec TUG or unable to do chair stand with arms crossed	Phase 1: 3 mo Phase 2: 7 mo/ 12 mo <i>Experimental</i> : PT home assessment and treatment, individualized exercise (arm and leg strengthening). Average 16 visits over 6 mos. Phone calls monthly after 6 mos. <i>Control</i> : health-related education, home visits, 1 phone call/mo.		<i>Self-report function</i> : Disability Score <i>Other</i> : Admission to nursing homes	Fall risk: Improved self-report disability at 7 and 12 mos, except for very frail. No change in nursing-home admission. Conclusion: Home-based assessment and treatment can decrease functional decline and frailty.	Total: 15/17 Internal validity: 8/10
Green 2002 ²²	N= 359 F:M 1:1 Age: 71/73 (mean for each group) Inclusion: ≥ 50 yrs, stroke at least 1 yr and	Phase 1: 3 mos Phase 2: 6/9 mos <i>Experimental</i> : individualized community PT for a maximum of 13 wks, minimum contact 3 visits	Falls: Number of falls	<i>Dynamic balance</i> : Rivermead Mobility Index <i>Gait</i> : 10 m walk <i>Self-report function</i> : Anxiety/depression, general health status, Barthel index	Falls: Improved, number of falls decreased Fall risk: Inconsistent—improved mobility, gait speed but not self-report health or social status at 3 mos. Gains did not persist at 6 and	Total: 12/17 Internal validity: 6/10

		persisting mobility problems (walk aid, fall in last 3 mos, unable to do stairs or slow gait speed)	<i>Control:</i> physical activity as usual (not described)		9 mos. <i>Conclusion:</i> Improvement in mobility and balance achieved after 3 months is not sustained 1 year later.	
Hinman 2002 ²³	<i>N</i> =97 F:M 3:1 Age range: 63–87 yrs Mean age: 72 yrs <i>Inclusion:</i> Able to ambulate independently, with or without aid	4 wks <i>Experimental:</i> (1) 3×/wk home exercise of illustrated balance and muscle strength (18 exercises, phone call reminders); (2) 3×/wk Biodex: challenges centre of gravity; various progressive displacements		<i>Dynamic balance:</i> BBS, reaction time <i>Gait:</i> 50 ft walk <i>Falls efficacy:</i> MFES	<i>Fall risk:</i> No change; sSmall gains in both exercise groups, but no significant differences among groups <i>Conclusion:</i> There was no short-term improvement in performance following balance training programme.	Total: 10/17 Internal validity: 5/10
Hofmeyer 2002 ²¹	<i>N</i> =35 F:M 4:1 Mean age: 80 yrs <i>Inclusion:</i> ≥65 yrs, needed assistance in transferring, walking, bathing, or toileting (equipment or person)	2 wks <i>Experimental:</i> 6 sessions of individualized functional training rising from the floor, 45 min, PT-led <i>Control:</i> placebo (group chair flexibility class)		<i>Functional task:</i> Floor rise task under different conditions (time, number completed), difficulty scale, symptom scale associated to the task	<i>Fall risk:</i> Improved on all outcomes <i>Conclusion:</i> A short movement-training intervention improved ability, decreased perceived difficulty, and decreased symptoms associated with the task; such an intervention may assist older adults at risk of falls.	Total: 11/17 Internal validity: 5/10
Hogan 2001 ²⁷	<i>N</i> =163 F:M 3:1 <i>Inclusion:</i> ≥65 yrs, fall in last 3 mos, ambulatory	1 yr <i>Experimental:</i> in-home assessment, treatment plan, exercise (attend at least 3 times group programme designed for those with fall risk—components not described); only for those deemed necessary <i>Control:</i> Treatment as usual (1 visit from recreation therapist)	Number of falls Emergency room/hospital admission		<i>Falls:</i> No change. <i>Conclusion:</i> Individualized assessment and treatment did not decrease number of falls or fall-related health care use.	Total: 11/17 Internal validity: 5/10
Li 2005 ²⁰	<i>N</i> =256 F:M 3:1 Age range: 70–92 yrs Mean age: 77.5 yrs <i>Inclusion:</i> ≥70 yrs, not involved in moderate or strenuous activity in previous 3 mos, community dwelling	6 mos <i>Experimental:</i> tai chi 3×/wk, 1 hr duration <i>Control:</i> placebo (stretching, seated and standing)	Time to first fall Number of falls Multiple falls	<i>Dynamic balance:</i> BBS, functional reach, DGI <i>Functional task:</i> TUG <i>Gait:</i> 50 ft speed walk <i>Falls efficacy:</i> SAFFE	<i>Falls:</i> Improved in experimental group <i>Fall risk:</i> All balance measures and SAFFE improved <i>Conclusion:</i> 6 months of tai chi improves balance and fear of falls; improvement is maintained 6 months post-intervention.	Total: 14/17 Internal validity: 7/10
Liu-Ambrose 2004 ¹⁵	<i>N</i> =98 100% F <i>Inclusion:</i> 75–85 yrs, female, low bone mass (OP or osteopenia)	25 wks <i>Experimental:</i> (1) group resistance training exercise 2×/wk, 50 min, extremities and trunk; (2) agility, balance, functional activities 2×/wk, 50 min <i>Control:</i> sham exercises (posture correction, stretching) 2×/wk, 50 min		<i>Muscle strength:</i> Isometric dorsiflexion strength (foot plate) <i>Dynamic balance:</i> Community Balance and Mobility Scale, reaction time <i>Self-report function:</i> PASE <i>Composite fall risk:</i> PPA—sway, quadriceps strength, reaction time, proprioception, visual edge contrast	<i>Fall risk:</i> Improved in total PPA for agility and resistance, but not for all components and not for dynamic balance and dorsiflexion strength <i>Conclusion:</i> Both resistance and agility training group programmes for 25 weeks can decrease fall risk in osteopenic women.	Total: 15/17 Internal validity: 8/10

(Continued)

Table 1 Continued

First Author/ Year	Participants	Intervention	Falls Outcomes	Fall Risk Outcomes	Results	Quality Rating
Lord 2005 ¹⁸	N=620 F:M 3:1 Mean age: 80 yrs Inclusion: ≥ 75 yrs, moderate to high fall risk as measured by PPA	Phase 1: 6 mos Phase 2: 12 mos Experimental: (1) extensive exercise intervention: assessment, individualized programme matched to deficits, 2 \times /wk exercise class (strength, flexibility, coordination, and balance), referred to eye care specialist and counseling; (2) minimal intervention: results given from fall risk assessment, home exercise sheets, suggestions to maximize vision and facilities where they could do exercises close to home Control: physical activity as usual	Number of falls	Functional task: Sit-to-stand Self-report function: SF-12 Composite fall risk: PPA	Falls: No change Fall risk: Improved in PPA between extensive programme and control, but not for balance; visual acuity and contrast sensitivity significantly improved in extensive group Conclusion: There was some improvement in fall risk with an extensive individualized intervention, but no significant decrease in falls.	Total: 13/17 Internal validity: 6/10
Morgan 2004 ²⁸	N=294 F:M 3:1 Mean age 81 yr Inclusion: ≥ 60 yrs, hospital admission or bed rest for 2 days or more in past mo	8 wks Experimental: exercise classes 3 \times /wk, 45 min, for 8 wks: muscle strength, balance, flexibility and gait in sitting and standing positions, PT led Control: physical activity as usual	Time to first fall Number of falls Postcard diaries returned every 2 wks	Dynamic balance: Tinetti's gait and balance assessment Self-report function: SF-36	Falls: No change between exercise and control, but difference in high vs. low physical function (i.e., risk of falls decreased for those with low physical function and increased for those with high physical function) Fall risk: No change Conclusion: An 8-week low-intensity programme may help decrease fall risk for lower-functioning adults following bed rest or hospitalization.	Total: 11/17 Internal validity: 5/10
Sattin 2005 ²⁴	N=311 F:M 30:1 Mean age: 80 yrs Inclusion: ≥ 70 yrs, ambulatory, transitioning to frailty based on Speechley/Tinetti classification and history of 1+ falls in past year	48 wks Experimental: tai chi 2 \times /wk for 60 min, progress to 90 min Control: wellness programme 1 \times /wk (fall prevention education)	Number of falls Monthly calendars	Falls efficacy: FES, ABC Covariates: Dynamic balance: Functional reach Gait: 10 m walk Self-report function: CES-D (depression scale), use of sedatives	Fall risk: Improved in falls efficacy at 8 mos and 12 mos, adjusting for baseline scores of other measures used as covariates; analysis of change in covariates not reported Conclusion: Tai chi over 48 weeks improves balance confidence compared to education.	Total: 13/17 Internal validity: 7/10
Steinberg 2000 ³¹	N=252 F:M 5:1 Inclusion: ≥ 50 yrs	1 yr Experimental: 4-group add-on approach: (1) presentation and video on home safety (2) #1 + 1-hr exercise class 1 \times /mo and video of exercise to take home (type of exercise not described); (3) #1 + #2 + home safety assessment; (4) #1 + #2 + #3 + clinical	Time to first fall Number of falls (near falls, slips, and trips) Daily calendar diary		Falls: Improved when groups 2–4 were combined and compared to control; no significant differences for individual group comparisons Conclusion: Community-based interventions can decrease falls; the best type of programme was not determined from this study.	Total: 9/17 Internal validity: 5/10

		assessment and advice on medical risk factors for falls				
Suzuki 2004 ¹⁶	N=52 100% F Age range: 73–90 yrs Mean age: 78/77 yrs (exp/control) Inclusion: not clear	Control: education only (#1) 6 mos Experimental: 10 1-hr exercise sessions once every 2 wks (strength, balance, tai chi) supplemented with home exercise Control: pamphlet and advice on fall prevention	Number of falls	Muscle strength: handgrip, knee extension (hand-held dynamometer) Dynamic balance: single-leg standing, tandem walk, functional reach Gait: 11 m timed walk	Falls: Improved at 20 mos for experimental group Fall risk: Inconsistent—improved for tandem walk and functional reach, no change for strength Conclusion: An exercise programme with minimal contact, supplemented with home exercise, can decrease falls and improve fall risk at 6 and 20 months.	Total: 11/17 Internal validity: 6/10
Wolf 2001 ⁴²	N=94 F:M 3:1 Mean age: 84 yr Inclusion: ≥75yrs, minimal loss of visual acuity, no acute illness, no PT in past mo, impaired balance	4–6 wks Experimental: 12 sessions of balance training; individualized PT treatment (systems approach), 2–3×/wk at home or PT department Control: attention only (e.g., individualized according to interests, handicrafts, games)		Dynamic balance: BBS, DGI Self-report function: anxiety/ depression scale Falls efficacy: Level of fear rated on visual analogue scale	Fall risk: Improved dynamic balance, but not sustained 1 yr later Conclusion: Individualized balance training can improve fall risk in the short term, but the improvement is not sustained 1 year later.	Total: 12/17 Internal validity: 6/10
Wolf 2003 ¹⁷	N=200 F:M 4:1 Mean age: 76 yrs Inclusion: ≥70yr, ambulatory, community dwelling	15 wks Experimental: (1) tai chi 2×/wk—group; (2) computerized balance training 1×/week—individual; both groups: contact time = 45 min/wk Control: attention only (weekly for 1 hr, general health education)	Time to first fall Multiple falls only Monthly calendar	Muscle strength: handgrip; hip, knee, and ankle isometric (hand-held dynamometer) Gait/Endurance: 12-min walk, cardiovascular status Self-report function: Instrument of Activities of Daily Living Scale, CES-D, mastery, perceived well-being Falls efficacy: FES	Falls: Improved in experimental group for multiple falls only Fall risk: Inconsistent—positive for handgrip and falls efficacy; both intervention groups improved in 12-min walk compared to control Conclusion: Tai chi can have favourable effects on psychosocial and physical indicators of falls and occurrence of multiple falls.	Total: 13/17 Internal validity: 6/10

ABC = Activities-specific Balance Confidence Scale; BBS = Berg Balance Scale; CAMOS = Canadian Multi-centre Osteoporosis Study Questionnaire; CES-D = Center for Epidemiological Studies Depression Scale; COP = centre of pressure; DGI = Dynamic Gait Index; FES = Falls Efficacy Scale; F:M = female to male; HAP = Human Activity Profile; MFES = Modified Falls Efficacy Scale; OT = occupational therapist; OP = osteoporosis; PASE = Physical Activity Scale for Elderly; PPA = Physiological Profile Assessment; SAFFE = Survey of Activities and Fear of Falling in the Elderly; SF-36 = 36-item Short Form Health Related Quality of Life Questionnaire; TUG = timed up-and-go

Note: Results are categorized as (1) *improved* or *positive outcome* (intervention showed significant improvement in primary outcomes measured); (2) *inconsistent* (some primary outcomes improved, but not consistently); or (3) *no change* (no significant differences control and intervention)

Table 2 Checklist of 22 Studies Reviewed for Population and Intervention

First Author/Study	Included aged >50 years	Included aged >65 years	Included aged >75 years	Inclusion: At least 1 fall risk factor*	Inclusion: Presence of a secondary condition**	Inclusion: Healthy*** Group	Intervention: Group	Intervention: Group and Individual Follow-Up****	Intervention: Individual and Home Follow-Up	Programme <6 months	Programme >6 months
Barnett ¹²				✓		✓	✓				✓
Brouwer ¹³		✓		✓		✓				✓	
Campbell ²⁹			✓	✓					✓		✓
Carter ¹⁴	✓				✓		✓			✓	
Clemson ¹⁹	✓			✓			✓				✓
Davison ²⁵				✓					✓		✓
Day ³⁰	✓					✓	✓			✓	
Devereux ⁴¹	✓					✓	✓			✓	
Gill ²⁶			✓	✓					✓		✓
Green ²²	✓				✓				✓		✓
Hinman ²³	✓					✓			✓ (phone call)	✓	
Hofmeyer ²¹		✓		✓					✓	✓	
Hogan ²⁷		✓		✓							✓
Li ²⁰		✓				✓	✓				✓
Liu-Ambrose ¹⁵			✓		✓		✓				✓
Lord ¹⁸			✓			✓	✓	✓			✓
Morgan ²⁸	✓	✓			✓		✓			✓	
Sattin ²⁴		✓		✓			✓				✓
Steinberg ³¹	✓			✓	✓	✓	✓	✓			✓
Suzuki ¹⁶			✓		✓	✓	✓	✓			✓
Wolf ⁴²			✓	✓					✓	✓	
Wolf ¹⁷	✓					✓	✓	✓		✓	

*Previous fall or decreased functional status; had to be clearly stated and measured using a standardized test.

**Conditions such as osteoporosis, stroke, arthritis, or hospital admission (any condition that might decrease functional status).

***Even if the inclusion stated that they did not exercise regularly, they were otherwise healthy.

****An individualized home programme was provided by a health professional in conjunction with the group intervention.

rising from a chair or rising from a chair and walking (i.e., timed up-and-go test); (3) balance (static or dynamic); (4) gait (i.e., velocity over a short distance); (4) fear of falls or falls efficacy; (5) self-reported functional status; and (6) a composite measure of several factors resulting in a fall risk score. All of these factors have been found to be associated with future fall risk.^{9(p.11),11}

Muscle Strength and Functional Tasks

Six¹²⁻¹⁷ of the 22 studies measured muscle strength at the hip, knee, or ankle. In only one study was a statistically significant improvement found in lower-extremity muscle strength in the exercise group following the intervention.¹⁴ The length of the intervention for these six trials ranged from 8 weeks to 1 year; frequency of the exercise programme ranged from as little as once every 2 weeks to twice per week. For functional tasks, two studies used the sit-to-stand test,^{12,18} two used the timed up-and-go test,^{19,20} and one used a floor rise task.²¹

Balance

Of the 22 studies included, 15 assessed balance, using a total of 16 different methods. Balance was assessed either statically, by measuring sway or centre of pressure excursion, or dynamically, by evaluating balance during functional activities as found in the Berg Balance Scale, Tinetti's Gait and Balance Assessment, or functional

reach. Nine of the 15 studies that assessed balance found a positive improvement or an inconsistent improvement (i.e., improvements were noted in some but not all balance measures). All those that measured balance included some aspect of balance training in the intervention, although the type, duration, and intensity of balance activity were not always described.

Gait

Gait was typically measured as velocity over a short distance (timed over 10 m). Alternatively, an endurance test, such as the 6- or 12-minute walk test, was used. Seven studies^{12, 13, 16, 20, 22-24} measured gait velocity over a short distance, yet only one study reported a positive effect of exercise (in a population of older adults diagnosed with stroke).²² The one study that included the 12-minute walk test reported a positive effect on cardiovascular status but no significant difference in distance walked following a twice-weekly tai chi intervention compared to once-weekly balance training and education.¹⁷

Composite Measures

In two studies, a composite measure of fall risk with established reliability and validity was used.^{15, 18} Improvement in the total score of the Physiological Profile Assessment (PPA) was reported in both studies,

but not all individual assessment components showed improvement.

Falls Efficacy and Self-Reported Function

Several different measures of fear of falls, falls efficacy, or balance confidence were used. The three studies that used a form of tai chi as the intervention^{17,20,24} all found improvement in falls efficacy or a reduction in the fear of falling. Thus, there were 10 studies that measured falls efficacy or fear of falling, and three of these included tai chi as the intervention. Only two other studies reported a significant improvement in falls efficacy;^{13,25} both of these included participants with a history of a fall in the past year or reported fear of falling. In these two studies, the influence of an educational component combined with exercise intervention was examined on the outcome of falls efficacy. A variety of methods was used to measure functional status and general health status with the SF-36 or SF-12,^{12,13,18,28} a disability score,²⁶ or other general health questionnaires.^{14,22} An improvement in general health status as measured by a disability score was reported in one²⁶ of these seven studies.

Falls

Falls typically were reported by participants using monthly mail-in postcards. Some studies used follow-up with phone calls. Adherence to reporting of falls was not always documented, nor was the cognitive status of participants described in order to delineate their ability to recall falls and fall-related events. Only 11 of the 22 studies reported using cognitive impairment, as measured by a standardized assessment tool, as an exclusion criterion.

Interventions

The interventions for each study are described in Tables 1 and 2 and summarized below:

1. Thirteen of 15 studies involving a group exercise intervention (87%) described programme objectives to improve strength and/or balance. Three of the interventions were exclusively tai chi, one was aquatic exercise, and the remaining 11 used land-based exercise programmes incorporating balance and resistance training.
2. Six of the 15 studies (40%) using a group exercise intervention provided some form of individual follow-up by a health professional, either a nurse, physician, physical therapist, or occupational therapist.
3. Positive results for falls and fall risk factors were observed for both group and individualized programmes; however, only five of the 22 studies in this review examined supervised individualized intervention programmes.

4. Thirteen studies evaluated interventions of at least 6 months' duration. Interventions across all 22 studies ranged from 2 weeks to 1 year in duration.
5. Eight of 14 studies that measured falls or fall rates had a positive outcome, four reported no change,^{14,18,27,28} and two found inconsistent results.^{17,29}
6. Seven of the eight studies with a positive effect on the reduction of *falls or fall rates* had an intervention lasting longer than 6 months.
7. Seventeen of 19 studies that measured fall risk found either a positive effect of exercise overall or improvement in only some fall risk factors. Only two studies reported no change in fall risk.^{23,28}
8. Both short-term and long-term interventions (<6 months or ≥ 6 months) demonstrated overall positive or partial effects on reducing *fall risk*.
9. In two studies that evaluated the effects of staged, multi-factorial interventions, using a combined approach of an exercise intervention with home modification, clinical assessment of fall risk factors, and/or referral to an appropriate health care professional, reduction of falls and fall risk improvement in the healthy older adult were reported.^{30,31} In contrast, Campbell et al.²⁹ reported that home modification alone was better at reducing falls than home modification plus exercise intervention in an older adult population with visual impairment.
10. Description of balance interventions lacked details regarding the progression, complexity, and duration of programmes. Generally, strength training was described in more detail than balance training.
11. Group exercise programmes ranged from 40 to 60 minutes in length.

DISCUSSION

The primary purpose of this review was to evaluate the impact of exercise programmes on decreasing falls and fall risk in community-dwelling older adults through a review of recent clinical trials. Our results suggest that exercise, delivered in a group, individual, or combined format, can reduce the number of falls as well as the risk of falling in older adults. The results of this review are similar to findings of previous reviews with respect to the effects of exercise on falls.⁵⁻⁸ A novel result of this review, however, is the finding that exercise, in both short- and longer-term programmes, is effective for reducing fall risk, as measured by a variety of fall risk measurement tools and by a composite fall risk score.

Five studies evaluated individualized supervised exercise interventions,^{21,22,26,29,42} four studies described interventions with combined approaches,^{18,27,30,31} and only three studies^{15,17,23} compared types of exercise (e.g., strengthening vs. balance or computerized balance vs. tai chi). As a result, we are unable to provide specific guidelines on best exercise interventions for reducing fall risk factors. A previous review by Gillespie et al.⁵ concluded that there was limited evidence that individual

exercise prescription is more effective than group exercise programmes delivered in the community for decreasing the number of falls. Of the 16 studies reviewed by Gillespie et al.,⁵ only 5 examined individually prescribed exercises. Our review included 20 studies not previously reported by Gillespie et al.,⁵ and, of these, only 3 used an individually prescribed exercise programme. Most RCTs continue to investigate exercise interventions using group formats. Reasons for the continued interest in group exercise may include the reduced costs of delivering group programmes as compared with more intensive, health professional-delivered individualized programmes, as well as the social networking that is encouraged by the group setting. Many study interventions combined group and individual exercise formats, which may not be representative of common clinical practice. In addition, it is unclear whether or not a combined format improved results. Future clinical trials should consider whether the formats being examined represent common clinical practice.

Although there was limited evidence that multifactorial interventions, including exercise, were more beneficial than exercise alone, two exceptions should be noted. Campbell et al.²⁹ found that an exercise intervention delivered in the home was not as effective as a home safety intervention for fall reduction in older adults with visual impairment. Further, combining exercise and home safety was no better than the home safety programme alone. Poor adherence to the exercise programme may have influenced their results. Further research is needed to elucidate whether exercise can reduce falls or fall risk factors in older adults with chronic conditions, as most studies to date have focused on healthy older adults. It should be noted that men are underrepresented in the studies to date. Further, there appear to be differences in the reporting and circumstances of falls for men and women,^{32,33} as well as variability in fall rates between the two genders. For example, one study reported higher fall rates for men than for women in rural communities.³⁴ More research is needed to determine whether there are gender-related differences in the effect of exercise interventions aimed at reducing falls and fall risk.

Previous reviews of the effect of interventions for fall prevention have been limited to samples aged 65 years or older. Only two studies in our review included adults younger than age 60. However, Steinberg et al.³¹ found a positive effect for combining exercise and home safety in adults aged 50 or older with no known fall risk factors. Future research should consider both the effect of starting age for the exercise programme as to its influence on falls and fall risk and whether some strategies are more or less effective in different age groups.

Although our review findings suggest that interventions lasting longer than 6 months are more likely to reduce the rate of falls, shorter exercise interventions

(i.e., less than 6 months) also have shown positive results in fall risk reduction. In the shortest exercise intervention (2 weeks),²¹ the authors reported improvement in getting up from the floor, a specific functional task related to falling and fall recovery. It is not known whether this short programme could influence other fall risk factors, such as balance, or reduce the number of falls. Improved balance was found in studies using interventions that ranged from as little as once per week for 8 weeks¹³ to once every 2 weeks for 6 months (with supplemented home exercise).¹⁶ Because of the wide range of balance outcome measures used, the lack of validity cited for some measures, the questionable ability of some of the measures used to predict falls, and the inconsistency in results across studies, no definitive conclusions can be made with respect to optimal intervention type or duration for improving balance. It is also unclear whether exercise performed less than twice per week is adequate to improve all fall risk factors. The results of this review suggest that once or twice per week may be adequate to influence balance, falls efficacy, and functional improvement but is unlikely to have a significant influence on muscle strength. Only one of the six studies that measured lower extremity strength found an improvement in strength compared to a control group.¹⁴ Further research is needed to delineate the optimal frequency, duration, and intensity of exercise programmes to influence fall risk. Given the potential lower cost of short-term interventions and issues related to patient adherence, future studies considering these factors would be beneficial.

The secondary objective of this systematic review was to present an updated synthesis of outcome measures used to assess fall risk in community-dwelling older adults. Our results suggest that a number of tools are used to measure fall risk. However, only 2 of the 19 studies that included measures of fall risk used the PPA, a valid, reliable tool that provides a composite fall risk score. Based on our systematic review findings, there does not appear to be any one tool that is more responsive in detecting changes in fall risk following exercise for the older adult population. Methods for measuring balance were extremely variable across the studies, with 16 different methods used among the 22 studies reviewed. This lack of standardization limits our ability to compare the findings for changes in balance across these studies.

Gait velocity over a short distance, which has been found to be associated with fall risk,³⁵ was used as an outcome measure in seven studies. Only one of these studies reported improvement in gait velocity following exercise intervention.²² This study investigated the influence of exercise in individuals who had experienced a stroke at least 1 year prior to the exercise intervention and who continued to present with slower gait velocity than expected for their age group or who had reported a fall in the past 3 months. For healthy, community-dwelling seniors without significant impairment of

mobility, gait velocity may not be expected to change appreciably as a result of exercise intervention, or there may be a ceiling effect. As well, a meta-analysis evaluating the effect of exercise interventions on gait speed found that interventions of higher intensity (>60% of 1 repetition maximum) and higher frequency (at least 3 times per week for 60 minutes or more) were more likely than lower-intensity, lower-frequency programmes to produce an improvement in habitual gait speed.³⁶ In fact, some authors have argued that increasing gait velocity in healthy seniors does not reduce fall risk.³⁷ Consequently, future researchers evaluating healthy older adults might consider not including this measure, whereas those studying individuals with gait impairment might find it an important and relevant outcome measure to include. In the only study that measured walking endurance over a longer distance (12-minute walk), improvement in systolic blood pressure was reported in an ambulatory population over age 70.¹⁷ This finding suggests that the mechanism of fall risk reduction in this population may relate more to aerobic capacity than to a specific gait parameter. Although there is an association between walking endurance and other measures of fall risk,³⁸ the relationships among aerobic capacity, fatigue, endurance, and falls are not clear.

Authors of a number of the studies failed to explain clearly how falls efficacy was measured or how the intervention was designed to influence it. Reliability and validity of the examiners and the tools designed to measure falls efficacy were not always provided. Further, several different terms were used to describe this construct, including “fear of falling,” “falls efficacy,” “balance confidence,” and “avoidance of activity due to fear.” No single tool seems to be optimal for evaluating falls efficacy. Notably, all three studies that used tai chi as the exercise intervention observed an improvement in falls efficacy. Two of these studies used the same outcome measure, the Falls Efficacy Scale (FES).^{17,24} The only other studies in which improvement in falls efficacy was reported used an additional educational programme designed to enhance falls efficacy in a population already fearful of falls or who had fallen in the past year. It is possible that tai chi has an additional psychological benefit of efficacy enhancement, different from other exercise programmes. One study¹⁷ compared twice-weekly tai chi to once-weekly balance training; a significant positive effect of tai chi on falls efficacy was reported, as compared with controls, but no significant effect for the once-weekly balance training programme was found.

Some studies used general measures of health status as outcomes, such as the SF-36, the Instrument of Activities of Daily Living, the Barthel Index, and the Center for Epidemiological Studies Depression Scale (CES-D), as well as measures of physical activity such as the Physical Activity Scale for the Elderly (PASE).

In some studies, exercise positively influenced these outcomes, whereas in others it did not. It is possible that general health and physical activity measures were not responsive enough to detect change, since most study populations included healthy community-dwelling older adults. Also, performance on a general health status measure may not be as strongly correlated with fall risk as are more specific measures of function.⁹ General health status, as measured by tools such as the SF-36, has been found to be related to falls efficacy in individuals residing in long-term care facilities.³⁹ Further research is needed to determine whether or not these outcome measures are appropriate for assessing the effects of fall-prevention programmes in community-dwelling seniors.

Outcomes related to number and rates of falls are highly dependent on the ability of participants to accurately recall falls during and following the intervention period. Although intact cognitive status is associated with increased accuracy of fall recall,⁴⁰ not all researchers measured the cognitive abilities of participants or included cognitive impairment as an exclusion criterion. Future studies should attend more rigorously to screening and reporting cognitive status in the sample studied. In addition, more frequent assessment and follow-up of participants may improve accuracy of recall.⁴⁰

The intent of this systematic review was to include more recent literature (published since 2000), and the findings should be considered along with those from earlier reviews. As noted above, we attempted to include a broader scope of populations commonly treated by physical therapists and to include studies that evaluated fall risk factors as opposed to fall rates. Our results with respect to the effectiveness of exercise in reducing falls and fall risk support findings from earlier reviews. In general, both group and individualized programmes were found to improve fall rates and fall risks compared to sham exercise or another non-exercise intervention, such as education or a control group. Because of the heterogeneity of the study samples reviewed and the wide variety of fall risk outcomes used in the 22 studies, we were unable to conduct a meta-analysis. Thus, this is a best-evidence synthesis of current literature.

Future clinical trials investigating the influence of exercise on falls and fall risk should consider the following recommendations:

- Further research is needed in populations with secondary conditions known to influence fall risk and should include greater representation of male participants to assess differences in risk associated with gender.
- Balance and falls efficacy measures should be clearly described, including aspects of the intervention designed to influence these outcomes.
- Interventions designed to improve balance need to be described more explicitly.

- Exercise programmes that may have a better capacity to enhance falls efficacy should be identified, as well as the populations best suited for these interventions.
- Further research is required to assess which balance-measurement tools are optimal for clinical trials in a community-dwelling older adult population.
- More studies should include valid, reliable composite fall risk measures that consider the multifaceted nature of fall risk.
- Gait velocity does not appear to be a responsive measure in trials of healthy community-dwelling elderly but may be more appropriate in populations with greater impairment of mobility. Further investigation of gait velocity and other gait parameters is warranted.
- Future studies should determine the relationship of aerobic capacity, endurance, and the effects of fatigue to fall risk.
- Fall recall is a concern with studies reporting fall numbers and rates, and inclusion of cognitive status screening is recommended for future studies.
- Optimal length of exercise programmes (i.e., number of months) and dose (including type, time per session, and frequency [times per week]) should be studied further.

CONCLUSION

The findings of this review suggest that both group exercise programmes and individualized exercise prescription can reduce falls in community-dwelling older adults. While improvements in fall risk factors can be observed in interventions lasting less than 6 months, programmes longer than 6 months in duration are more likely to reduce the number and rate of falls. The tools used to measure fall risk, particularly balance, vary widely among studies, and there are currently no tools available that optimally predict falls. There is a need to investigate older adult sub-groups with chronic conditions such as stroke and arthritis that may increase fall risk, and the ideal type, duration, and frequency of exercise to reduce falls and fall risk is still unknown.

KEY MESSAGES

What Is Already Known on This Subject

Fall risk is one of the priority health concerns for physical therapists assessing and treating the elderly client. Although there has been a surge of recent randomized controlled clinical trials evaluating exercise interventions to prevent falls and improve fall risk, there are still no best-practice guidelines regarding type, frequency, intensity, or duration of exercise to prevent falls or the optimal outcome measures to evaluate fall risk.

What This Study Adds

This review includes the results of recent high-quality evidence from randomized controlled clinical trials on the influence of exercise interventions in decreasing fall risk in older adults. Our findings are in agreement with the findings of previous reviews, suggesting that exercise, delivered in either an individualized or a group format, can decrease fall rates and fall risk. Recommendations for future research will help researchers and clinicians to focus their efforts on identifying best-practice outcome measures and intervention methods for different target populations.

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APPENDIX A: QUALITY RATING CRITERIA USED FOR REVIEWS¹⁰

Instructions to Reviewers:

Answer YES, NO or DON'T KNOW, operationalization is in italics, also refer to van Tulder et al.¹⁰ Comments may be added as needed.

Patient Selection

- a. Were the eligibility criteria specified? *i.e., age, gender, specific condition or clear inclusion criteria*
- b. Treatment allocation: (1) Was a method of randomization performed? (2) Was the treatment allocation concealed?
- c. Were the groups similar at baseline regarding the most important prognostic indicators? *i.e., fall risk factors, age*

Interventions

- a. Were the index and control interventions explicitly described? *i.e., others could replicate the intervention*
- b. Was the care provider blinded to the intervention?
- c. Were co-interventions avoided or comparable?
- d. Was the compliance acceptable in all groups? Take into consideration length, intensity, duration of intervention
- e. Was the patient blinded to the intervention?

Outcome Measurement

- a. Was the outcome assessor blinded to the intervention?
- b. Were the outcome measures relevant? Includes falls or fall risk variables
- c. Were adverse effects described?

- d. Was the withdrawal/drop-out rate described and acceptable?

Follow-Up

- a. Was a short-term follow-up measurement performed?
Was a long-term follow-up measurement performed?
- b. Was the timing of the outcome assessment in both groups comparable?

Statistics

- a. Was the sample size for each group described?

- b. Did the analysis include an intention-to-treat analysis?
- c. Were point estimates and measures of variability presented for the primary outcome measures?

INTERNAL VALIDITY = 1 point for each of b, e, f, g, h, i, j, l, n, p = 10 maximum

DESCRIPTIVE CRITERIA = 1 point for each of a, c, d, k, m = 5 maximum

STATISTICAL CRITERIA = 1 point for each of o, q = 2 maximum